

REMARKS / ARGUMENTS

Claims Pending

Claims 1-20 were pending but have been cancelled by amendment herein. Claims 21 and 22 have been added by amendment. Thus, claims 21 and 22 are now pending.

Claim Rejections – 35 USC 103

Claims 1-14 are rejected under 35 USC 103(a) as being unpatentable over Gupte et al. (US5685294) in view of Hochrainer et al. (US5947118).

The rejections of claims 1-14 are rendered moot by the cancellation of these claims. New claims 21-23 are believed to be patentable over Gupte and Hochrainer for the reasons that follow.

The new claims are Jepson-type and include the transitional phrase “wherein the improvement comprises”. The text preceding this transitional phrase describes what is admitted to be prior art.

New claim 21 is intended to cover the invention in the form of a combination of inhaler device and medicament capsule. Claim 22 is directed to just the inhaler device in accordance with the invention.

It will be observed that the portion of claim 21 that precedes the transitional phrase essentially describes the combination of capsule and medicinal powder inhaler device that is taught by Gupte et al. It also corresponds to the description of the prior art that is given in the specification of the present application, at page 1, line 26 through page 2, line 23.

As will be apparent from the Jepson format used in claim 21, the invention resides in the improvement that is described after the transitional phrase. That is to say, the difference between the prior art combination of Gupta et al. and that of the invention is that the

combination of the invention is improved by the further inclusion of "raised elements on either the inner surface of said capsule chamber or the outer surface of said capsule, which raised elements align the axis of the capsule with the axis and the capsule chamber and which constrain the capsule, when it vibrates within the capsule chamber, to move back and forth along its longitudinal axis with essentially no transverse movement."

Claim 22 is directed to an inhaler device in accordance with the invention wherein the raised elements are on the inner surface of the capsule chamber.

Support for the claim language that follows the transitional phrases in claims 21-23 is to be found in the specification at page 1, lines 17-22; page 4, lines 1-16; page 4, line 28-30; page 9, line 13 through page 11, line 24; page 16, line 22 through page 17, line 10; as well as the drawings.

Admittedly, the combination of capsule and inhaler device provided by the invention is structurally very similar to that of the prior art. The only structural difference is that combination of the invention includes raised elements on either the inner surface of the capsule chamber or the outer surface of the capsule. Nevertheless, this seemingly modest structural change produces a significant improvement in the functioning of the combination of the capsule and inhaler device. The raised elements align the axis of the capsule with the axis and the capsule chamber and constrain the capsule, when it vibrates within the capsule chamber, to move back and forth along its longitudinal axis with essentially no transverse movement. (When the prior art combination of Gupta et al. is employed there is a substantial transverse component in the vibration of the capsule.) Causing the capsule to vibrate in a substantially longitudinal manner, without substantial transverse vibration, has been found to improve the emptying of the capsule and thus the delivery of the medicament from the capsule to the patient. Thus, the specification states, at page 13, lines 4-12:

The inhaler according to the invention allows the pharmaceutical composition to be delivered more reliably with a lower standard deviation

compared with the devices known from the prior art. Compared with many devices it also has the additional advantage of better breaking up of any clumps. In fact, the micronised pharmaceutical compositions in the capsules have a tendency to form clumps. These clumps are therapeutically undesirable as it is important for the pharmaceutical composition to be distributed as finely as possible. When the inhaler according to the invention is used the clumps are substantially destroyed.

Hochrainer et al. do not provide any teaching that would motivate one skilled in the art to modify the prior art combination of Gupta et al. in a manner that would yield the improved combination of the invention.

Hochrainer et al. describe an inhaler device that includes a capsule holder for the insertion and fixing of pharmaceutical capsules. The capsule holder consists of a plate with a recess in which there are at least three ribs arranged parallel to the central axis and at unequal spacings from one another, between which the capsules can be clamped both by their upper part and by their lower part in such a way that they do not fall out during normal handling but can readily be removed. It is important to note that the recess of Hochrainer does not correspond to the capsule chamber of the invention. The capsule chamber of the invention (as well as the prior art represented by Gupta et al.) is a plenum through which the patient draws a stream of air. This stream of air entrains medicament which emanates from a capsule placed within the capsule chamber, forming a mixture of air and medicament. The recess of Hochrainer is not a plenum through which air may be drawn. Rather, it is a compartment for storing a capsule until the patient needs to administer the medicament inside the capsule. At such time, a patient using the device of Hochrainer transfers the capsule from the recess to a capsule chamber. The ribs within the recess of Hochrainer firmly retain the capsule in the recess, so that it does not fall out during normal handling. (Imagine the sort of patient who would typically use an inhaler device of sort under discussion. He or she is likely to be elderly and to have impaired manual dexterity. It would be easy for this sort of patient to accidentally dump medicament capsules upon the ground if they are not firmly retained within the storage

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recesses of the inhaler device.) Thus, Hochrainer et al. address a problem of medicament storage, not medicament administration.

In contrast, by providing raised elements on either the inner surface of the capsule chamber (which is a plenum through which air flows) or on the outer surface of the capsule, the present invention addresses the problem of medicament administration. It improves the administration of the medicament. There is nothing in the teaching of Hochrainer et al. that suggests the improvement provided by the present invention.

It is respectfully urged that the invention as now claimed is patentable over the teachings of Gupta and Hochrainer.

#### Rejections of Claim 15-20

The rejections of claims 15-20 are rendered moot as these claims have been canceled and have no counterparts in the new claims.

#### Conclusion

It is respectfully urged that all claims now pending are allowable and that the application as a whole is in condition for allowance.

Respectfully submitted,

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